

REMARKS

Status of the Claims

Claim 12 and 13 have been cancelled and the limitations of claims 12 and 13 have been incorporated into claim 5. Also note that the "comprising" language of claim 5 has been substituted with "consisting essentially of". It is believed that no new matter has been added. Claims 5, 7-11 and 16-19 remain pending (other "amendments" are discussed below).

35 U.S.C. 112, second paragraph rejection

The rejection of claims 7, 8 and 16-19 (and previous Advisory Action) appear to indicate that the supplemental response of 13 February 2003 was not considered. The status of the claims indicated above would be the status of the claims if both the 11 February 2003 and the 13 February 2003 amendments were entered.

35 U.S.C. 102(b) rejection

Claims 5 and 7-13 were rejected by the examiner as being anticipated by Thomas et al. (U.S. Patent 5,610,130). The applicants request reconsideration in light of the claims as amended and because:

- (1) Thomas et al. fails to teach every element of the applicants' claimed invention; and
- (2) Thomas et al. is not enabling for the applicants' claimed invention; and
- (3) Thomas et al. does not adequately show possession of the applicants' claimed invention.

Thomas et al. fails to teach every element of the applicants' claimed invention

MPEP 2131 states that to anticipate a claim, the reference must teach every element of the claim, i.e. "The identical invention must be shown in as complete detail as is contained in the...claim." see *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d, 1913, 1920 (Fed. Cir. 1989). It has also been held that for a proper anticipation rejection, the reference "must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference." see *In re Arkley*, 455 F.2d 586, 587, 172 USPQ 524, 526 (CCPA 1972). However, Thomas et al. does not teach every element in as complete a detail as is contained in the applicants'

claim, i.e. Thomas et al. contains too many components and too many limitations in their oil-in-water microemulsions to be considered to be anticipatory of the applicants' claimed invention, i.e. the teachings of Thomas et al. are too far removed from that of the applicants' claimed invention to be considered anticipatory.

The Thomas et al. reference describes a surfactant mixture (emulsifier mixture) which comprises of (i) an anionic surfactant; (ii) an ethoxylated glycerol-based nonionic surfactant mixture; and (iii) a salt of a multivalent metal cation and a water-soluble cosurfactant component (C) - (see e.g. col. 3, lines 10-23). The specific emulsifiers listed in section (a) and/or (b) of applicants' claim 5 would not be considered to be equivalent to the combination of elements listed by Thomas et al. as being part of their microemulsion, i.e. (a) cetareth-12, cetareth-15, cetareth-20, glyceryl stearate, glyceryl isostearate, stearic acid, isoceteth-20, sorbitan monoisostearate and mixtures thereof with or without an emulsifier which does not have the properties of the emulsifiers listed in (a).

The examiner mentions that stearic acid could be a part of Thomas et al.'s invention ("...from about 0 to about 5% of a fatty acid"). In addition to this being an optional ingredient within the teaching of Thomas et al., Thomas et al. never teaches the degree of specificity required by the applicants' claims and as such fails the "complete detail", "clear and unequivocal" standard for anticipation.. However, even if the examiner's assertion about stearic acid was accepted as true, this would only represent a teaching from Thomas et al. that they have a surfactant mixture of (i)-(iii), (C) **and stearic acid** (at least five essential components plus the insect repellent) vs. applicants claimed invention (only two essential components plus the insect repellent).

No indication that Thomas et al. is enabling for applicants' claimed invention

Whether an invention is anticipated is a question of fact. *Hoover Group, Inc. v. Custom Metalcraft, Inc.*, 66 F.3d 299, 302, 36 USPQ2d 1101, 1103 (Fed. Cir. 1995). In addition, it is well known that "A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354, 65 USPQ2d 1385, 1416 (Fed. Cir. 2003).

The applicants' claims as amended teach the concept that oil-in-water microemulsion can be formulated by using the emulsifier described by (a) of claim 5 with or without a W/O emulsifier which does not have the properties of the emulsifier of (a). There is no indication from the teachings of Thomas et al.

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that any of their required elements (i.e. (i)-(iii) and (C)) could be eliminated without adversely affecting their ability to form "stable oil-in-water microemulsions", i.e. a fair reading of Thomas et al.'s disclosure is that it is the collective combination of all the elements described by Thomas et al. which forms the stable oil-in-water microemulsion. This is buttressed by the fact that not only does Thomas et al. require additional elements for their oil-in-water microemulsions, but they also require specific relationships between some of these elements (e.g. ratio of (i) : (ii) is from about 1:1 to about 5:1 and the salt of a metal multivalent cation in an amount sufficient to provide from 0.5 to 1.5 equivalents of cation per equivalent of (i)), i.e. Thomas et al. discloses criticality for the relationship of elements and therefore, the Thomas et al. reference imposes a restriction on the degrees of freedom as to how their teachings can be interpreted. Therefore, one of ordinary skill in the art cannot take an expansive view of the teachings of Thomas et al. either with regard to the amount of ingredients present or with the addition or subtraction of the required ingredients which constitutes their oil-in-water microemulsion.

Furthermore, the state of the art for oil-in-water microemulsions is such that the elements and limitations without further factual support would suggest that Thomas et al. is not enabling for the applicants' invention as claimed, i.e. in the applicants' response of 1 August 2002, an exhibit was provided to the examiner which showed a phase diagram for a basic three component system; even in this "simplified" environment, changes in structure could occur when varying conditions. Thomas et al. teaches a more complex system and as such it cannot be presumed that their teaching would be predictive of the applicants' claimed invention.

There is no evidence on the record which suggests one of ordinary skill in the art could remove elements from Thomas et al.'s disclosed invention in the manner described by the examiner. It is also instructive to note that Thomas et al. appeared to have voluntarily made these element and ratio disclosures and that this was not based upon a response to prior art, i.e. even their broadest conceivable interpretation of Thomas' recitation of their invention (i.e. their "Summary of the Invention" section) includes these elements and ratios (see col. 3, lines 6-25).

No indication that Thomas et al. "possessed" applicants' claimed invention

There are also serious doubts that it was possible for Thomas et al. to have "possessed" the applicants' claimed invention. It has recently been ruled that "[t]he disclosure in an assertedly anticipating reference must be adequate to enable possession of the desired subject matter. It is insufficient to name

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or describe the desired subject matter, if it cannot be produced without undue experimentation. The principles underlying application of the criteria of enablement to the content of the prior art were discussed in *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985):

It is well settled that prior art under 35 U.S.C. 102(b) must sufficiently describe the claimed invention to have placed the public in possession of it. Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention. Accordingly, even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it is not enabling. It is not, however, necessary that an invention disclosed in a publication shall have actually been made in order to satisfy the enablement requirement.

Id. at 533, 226 USPQ at 621. See also *In re Borst*, 345 F.2d 851, 855, 145 USPQ 554, 557 (CCPA 1962) ('the disclosure must be such as will give possession of the invention to the person of ordinary skill. Even the act of publication or the fiction of constructive reduction to practice will not suffice if the disclosure does not meet this standard.').” *Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education and Research*, pg. 8, No. 00-1467 (Fed. Cir. Oct. 3, 2003), available at <http://www.fedcir.gov/opinions/00-1467a.doc>.

Thomas et al. never suggests that they possessed anything beyond their narrow construction of their claimed composition. Referring again to the state of the art and the exhibit from the 1 August 2002 response, it appears that one of ordinary skill in the art would have to undergo undue experimentation in order to modify the invention of Thomas et al. to match the applicants' claimed invention.

Furthermore, Thomas et al. teaches that the use of a fatty acid as a “foam suppressant” (see col. 13, lines 7-10). While it is not necessary that the required element act in the same manner as that described in the applicants' invention, this description by Thomas et al. clearly does not envision the use of a fatty acid (e.g. stearic acid) as being an emulsifier and as such an element which is critical for the formation of a stable oil-in-water microemulsion. To arrive at the invention of Thomas et al. would still require the addition of other ingredients in order to be enabled and as such there is no factual support for an argument that Thomas et al. teaches the limited number of elements to form an oil-in-water microemulsion as is claimed by the applicants.

Therefore, since Thomas et al. does not teach each element of the applicants' claims as amended, does not show that their teachings would be enabling for the applicants' invention or show any indication of “possession” of the applicants' claimed invention as amended, the applicants believe that the

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examiner would be justified in withdrawing this rejection.

35 U.S.C. 103(a) rejections

- (1) Claims 16 and 17 were rejected by the examiner as being obvious over Thomas et al., *id.*, in view of Moore et al. (U.S. Patent 6,063,746).

The response to the Thomas et al. reference is to be considered repeated here. The Moore et al. reference is relied upon for teaching the specific elements represented by claims 16 and 17. However, it is not enough that all of the claimed elements can be found in the prior art if proper motivation cannot be established to combine the teachings of the references.

It is well known that it is essential that the decisionmaker forget what he or she has been taught at trial about the claimed invention *and cast the mind back to the time the invention was made...* to occupy the mind of one skilled in the art *who is presented only with the references*, and who is normally guided by the then-accepted wisdom in the art." *Id.* One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." see *In re Fine*, 5 USPQ2d 1596, 1599, 1600 (Fed. Cir. 1988).

In the present situation, going back to 2 October 2000 (the filing date of the application - filing receipt incorrectly lists this as 3 October), if one were to place the Thomas et al. and Moore et al. references before one of ordinary skill in the art on this date without the benefit of the claims which are pending in the application, what would've possessed that skilled artisan to make the selection as asserted by the examiner?

The court in *In re Rice*, 178 USPQ 478, 480 (CCPA 1973) when presented with a similar situations stated, "...the board said, referring to the appellant's ingredients, 'It should be noted that an infinite number of combinations is possible.' Accepting that as an approximation to the truth, we fail to see the obviousness in devising appellant's.....[invention] as claimed." *Id.* at 480.

Both the Thomas et al. and Moore et al. teach an almost limitless number of combinations for their respective elements which constitute their invention. There is no reason to believe that one of ordinary skill in the art would have arrived at the specific limitations of claims 16 and 17 without the template provided by the applicants' claims.

- (2) Claims 18 and 19 were rejected by the examiner as being obvious over Thomas et al., *id.*, in view of Klier et al. (U.S. Patent 4,127,672). It is believed that the rejection of claims 18 and 19 would stand or fall with the rejection of independent claims upon which they are based. This rejection is conceded should the independent claims remain rejected.

Obviousness-type double patenting rejection

Although both applications have the same effective filing date and represent a parent-child relationship, patent term adjustment (PTA) could result in one patent having a later termination date than the other patent. However, the examiner is reminded that MPEP 822.01 recites that "If the 'provisional' double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the 'provisional' double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent. See also MPEP § 804.01 and § 822."

Therefore, if this application is allowed first, it is believed that no terminal disclaimer is necessary.

Closing

Applicants also believe that this application is in condition for allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Respectfully submitted,

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